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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/689,455 | 10/20/2003 | Jurgen Luders | CCF-6352NP | 4175 |
| 26294 | 7590 | 02/22/2006 | EXAMINER | |
| TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVEVLAND, OH 44114 | | | ROBERTS, DARIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/689,455 | Applicant(s) LUDERS ET AL. | |
| | Examiner Darin R. Roberts | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/20/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-20 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/24/2004</u> . | 6) <input checked="" type="checkbox"/> Other: <u>10/20/2003</u> . |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-4, 12, 13, 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 2-4 are directed toward the claiming of structures being in contact with or implanted within the body, such claiming amounts to an inferential recitation of the body, which renders these claims non-statutory.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7 & 10, 12, 13, 15-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Schiff et al. (US 20030097159 A1).

In reference to **claims 1, 10, 16, & 19**, the Schiff et al. publication teaches the electrical stimulation of white matter within the brain via an electrode (see pp. [0070]). The ability to recruit non-white matter appears to be an inherent property of the Schiff

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device depending upon the placement of the electrode relative to the non-white matter and the extent to which one would alter the energy parameters of the device (such as increasing the amplitude or frequency) to recruit a larger amount of the desired brain tissue.

In reference **claims 2-4, 12, 13, 15**, the bodily tissue spoken of appears to be inherent to the human brain.

In reference to **claim 5**, the Schiff et al. publication teaches the use of implantable multipolar electrode with "an implantable pulse generator that can be a radiofrequency controlled" (see pp. [0028]).

In reference to claims **6, 7, 17, & 18**, the Schiff et al. patent teaches the multipolar electrode contacts should allow for adjustment of frequency (or "rate"), amplitude, and pulse width within at least the following respective ranges: about 2-200 Hz (see pp. [0028]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8, 11, 14, & 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff et al. (US 20030097159 A1).

In reference to **claims 8, 14 & 20**, the Schiff patent does not teach the use of a stimulator possessing a generally cylindrical body possessing an electrode within the internal portion of the body of the electrode as well as endoscopy, however, such a design is quite common in the art.

Thus it would have been obvious to one of ordinary skill in the art to use such a design to allow for eased access to the white matter of the brain and direct the electrode toward the desired stimulation site. Stimulation of the fornix, corpus collosum or the temporal stem would also be possible based on such a shape.

In reference to **claim 11**, the Schiff publication does not expressly state that one must first determine the location of white matter within the brain, however, Schiff does teach the stimulation of white matter.

Thus determining the location of non-white matter would have been obvious to one of ordinary skill in the art to assist in the location of white matter tissue and the improper stimulation of non-white matter.

Allowable Subject Matter

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The examiner has chosen to site the DiLorenzo (US 6366813 B1) patent because it speaks on cylindrical stimulator bodies possessing electrodes. The examiner has also chosen to site the Guthrie et al. (US 5230623 A) patent due to the fact that it speaks on the use of an endoscope.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571)272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

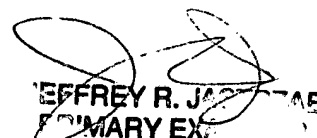
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Darin Roberts
Patent Examiner
Art Unit 3762

D. R.


JEFFREY R. JACOB
PRIMARY EX
2/16/06